INFLATABLE SPECULUM

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Abstract of **WO9724975**

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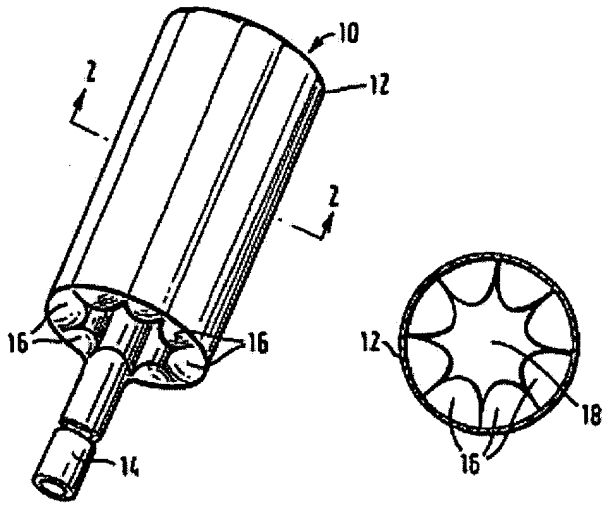

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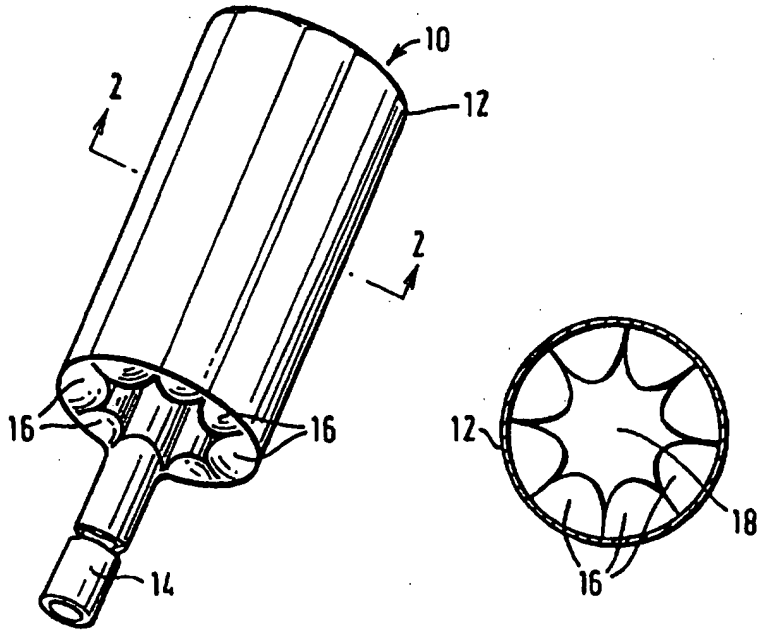

(57) Abstract

An inflatable vaginal speculum (10) comprising an inflatable elongate member (12), the elongate member (12) being adapted for insertion into the vagina when uninflated, the inflation of the elongate member creating a passage (18) through the member (12) which resists occlusion due to the force applied to the member by the vaginal walls. There is further provided a means for inflating the speculum.

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INFLATABLE SPECULUM

The present invention relates to a vaginal inflatable speculum. The speculum of the present invention is adapted for insertion into the vagina in its uninflated state, whereupon is it inflated to enable viewing of the uterine cervix. The invention also relates to a connector to enable inflation of the device.

Speculums of the prior art typically consist of two curved plates which are adapted for insertion into the vagina. The plates are then moved apart enabling the cervix to be inspected and the material required for pap smears to be taken. US-A-4,766,887 describes such a device. While these prior art speculums are quite adequate in performance, some women find the use of such devices unpleasant. Furthermore, the operation of the device is proximal to the vaginal opening, which can make adjustment of the locking parts difficult. The present invention seeks to provide an alternative to such prior art speculums which is introduced into the vagina in an unexpanded form and then expanded in situ.

WO93/07800 provides an expandable speculum, which comprises a series of interconnected tubular cells. Air is used to expand the speculum. However, there is a need for a speculum construction which can counteract the strong forces of the vaginal wall muscles.

There is also a need for a simple method of securing the uninflated device for insertion into the body, and also for connecting the device to the inflation means.

In one aspect, the present invention consists in an inflatable speculum comprising an inflatable elongate member, the elongate member being adapted for insertion into the vagina when uninflated, the inflation of the elongate member creating a passage through the member which resists occlusion due to the force applied to the member by the vaginal walls.

In a preferred form, the inflatable speculum comprises an elongate member, an array of inflatable tubes extending along the inner surface of the elongate member, and an air inlet means to enable inflation of the chambers characterised in that the inflatable chambers are arranged such that, upon inflation, they bear against each other so as to hold the elongate member open and provide a clear passage through the member.

The inflatable speculum of the present invention may be formed of any of a number of materials which collapse upon deflation and expand when inflated. Examples of such material include silicon, rubber, P.V.C., film, treated fabric and polypropylene film. It is presently preferred, however, that the inflatable speculum is made of laminated polyethylene and nylon.

As stated above, it is essential that the inflation of the speculum provides a clear passage through the speculum (lumen) through which the cervix may be inspected. The overall shape of the speculum when inflated outside the vagina will generally be conical. However, it is probable that when the speculum is inflated within the vagina it will be roughly cylindrical in shape due to the increased forces applied by the vaginal walls to the end of the speculum proximal to the labia.

The speculum may be inflated by any number of means, including a sac or syringe of known swept volume. However, it is presently preferred that the inflation means is an air pressure insuflator bulb similar to that used in blood pressure meters.

Detailed Description of the First Aspect of the Invention

In order that the nature of the present invention may be more clearly understood, preferred forms thereof will be described with reference to the following figures:

Fig. 1 shows a schematic drawing of a preferred form of the speculum of the present invention.

Fig. 2 is a view taken along line 2=2 of Fig. 1.

Fig. 3 shows another embodiment of the inflatable speculum of the present invention.

Fig. 4 shows the speculum of Fig. 3 laid flat prior to being made into a cylindrical shape;

Fig. 5 shows another embodiment of the inflatable speculum of the present invention; and

Fig. 6 shows how the device may be packaged for insertion.

As shown in Fig. 1, the inflatable speculum 10 consists of an elongate member 12 and air inlet means 14. As is shown more clearly in Fig. 2, an array of inflatable chambers 16 extend along the inner surface of the elongate member 12. The array of chambers are interconnected to allow passage of air through the chambers.

When the inflatable chambers 16 are inflated (as shown in Figs. 1 and 2), the individual inflatable chambers 16 bear against each other preventing the occlusion of passage 18 which extends through the elongate member 14. The feature of the individual inflatable

chambers 16 bearing against each other as in an arch, results in improved mechanical performance and greater resistance of the occlusion of passage 18 due to force applied to the elongate member 14 by the vaginal wall. This feature in the exemplified devices arises from the positioning of the inflatable chambers along the inner surface of member 12. A simple array of chambers joined along their widest points will not provide such mechanical strength.

As is shown in Figs. 1-4, the inflatable chambers may extend longitudinally along the inner surface of the elongate member. As shown in Fig. 5, however, it is also possible for the inflatable chambers to extend diagonally down the elongate member. The diagonal configuration of the chambers is preferred as this provides greater circumferential strength.

As will be recognised by those skilled in this field the distance between adjacent inflatable chambers should be kept to a minimum so as to provide greater strength in the "arch" thereby resisting occlusion by the vaginal wall muscles. Similarly, the cross-sectional area of the inflatable chambers should not be too small as this will also lead to decreased strength.

As is more clearly shown in Fig. 4, when deflated, the speculum of the present invention is quite small and may easily be rolled or folded for insertion into the vagina prior to inflation. The rolled or folded inflatable speculum may be inside a cardboard tube or other sheath such as used in TAMPAX® tampons to facilitate insertion, but may be retained in the rolled or folded condition by means of weak welds which would separate during inflation following insertion.

Preferably the speculum of the present invention is folded on itself and retained by an extended piece of material which wraps around the uninflated device, the extended piece of material being contiguous with the main member 12 of the speculum. An integral cap may also be provided to streamline the end of the folded speculum for insertion. In order to retain the wrapping material and cap in position, frangible welds are provided.

The wrapped device is more clearly shown in Figs. 6a - 6e.

Fig. 6a shows the speculum laid flat after moulding. An extended piece of material 61 is contiguous to one end of the member 12. A cap 62 in the same material is also present. Line AA' is securely seam welded to line BB'. This provides the useable speculum shown, partly inflated for ease of illustration, in Fig. 6b. The inflating tail 64 extends from the main body of the speculum.

In order to wrap the device, air is removed from the chambers 16. Because of its construction, the speculum collapses in on itself, Fig. 6c. The extended material 61 is wrapped around the deflated speculum, and attached back on itself by frangible welds, e.g. along line CC' and DD'. The cap 62 is similarly welded. The tail can be folded and spot welded back onto the wrapping member. The end results is a tidy package as shown in Fig. 6e.

In use, the tail is pulled away. The inflation means is inserted into the end of the tail. The device is inserted into the vagina. As air is pumped in, the inflatable chambers expand, and the frangible welds break apart. The device is fully inflated.

An advantage of the tail 64 is that the inflation means can be operated away from the patient.

After use, the speculum can be thrown away.

Although the speculum of the present invention has been described for vaginal inspection, the device can also be adapted for use in the other passageways, e.g. the rectum.

The present invention further relates to a Spigoted Connector of the type for connection with a socket, typically a socket within a valve which permits fluid flow. More particularly, the present invention is directed towards a spigoted connector in the form of an adaptor of the type having a longitudinally extending spigot (usually a nozzle) for insertion in such a valve.

Connectors of this type usually rely on frictional forces to restrain the spigot within a socket once inserted and are usually used to connect inflator devices to a wide variety of objects such as tyres, balls, mattresses, inflatable boats and speculums. Such connectors usually have an end connection for attachment to an inflator device, such as a hand pump, with a non return valve, where such non-return valves prevent the pressurised fluid within the inflated body from escaping. In use, such connectors are often used to inflate objects to high internal pressures. However the pressure to which these objects can be inflated is limited by the frictional forces exerted between the spigot and the socket. This is particularly relevant in the case of sockets made of a deformable material such as rubber or plastics, whereby the internal pressure of the inflated object may force the walls of the valve to expand and thus force the spigot out of the valve. Attempts to overcome this problem have included applying locking means which physically engage the valve to the connector but these often involve complex mechanisms which

are difficult to incorporate in non rigid sockets.

It is therefore, an object of the present invention to provide a spigoted connector of the type discussed above which alleviate the aforementioned problem in a simple, efficient and relatively inexpensive manner.

According to the present invention there is provided a spigoted connector comprising a longitudinally extending tube having a spigot at one end thereof, said tube extending through a support body and a resiliently deformable seal means whereby said seal means is disposed between said body and said spigot, and displacement means being provided to displace said body longitudinally relative to said tube towards the spigot causing said body and spigot to engage and stress the seal means to deform it radially outwardly relative to the tube for engagement with a socket in which the spigot may be received.

The displacement means may comprise a first cam surface on the tube with a second cam surface on an inner cam surface of the body so that relative rotation between the body and the tube will cause the first and second cam surfaces to come into engagement with one another and effecting relative longitudinal displacement between the tube and the body, forcing the body towards the spigot. Usually the connector will also comprise a retaining means for restraining the body from longitudinal displacement away from the spigot when the seal means is engaged and stressed between the body and the nozzle, therefore maintaining the seal means in its deformed state. It is envisaged that this retaining means will usually comprise a resiliently deformable projection on the tube which will snap engage with a shoulder formed on the inner surface of the body once the body has been displaced a predetermined

distance longitudinally in a direction towards the spigot.

Alternatively, the displacement means may comprise an external thread means carried on the tube engaging with an internal thread means on an inner surface of the body so that rotation of the body relative to the tube will effect relative longitudinal displacement between the tube and the body the direction of this longitudinal displacement being dependent on the direction of rotation of the body relative to the tube.

In the preferred form of the present invention the seal means will be compressed between the body and the spigot in order to deform the seal means radially outwardly relative to the tube, although it is also envisaged that the body or the spigot may carry a cam surface which can engage the seal means and apply an expansive force outwardly relative to the tube to deform the seal means. Usually, the seal means will be substantially spherical and will usually comprise an elastomeric material, preferably silicone rubber.

The spigot will usually comprise a nozzle which will have a circular cross section which increases in diameter as it extends longitudinally inwardly from the end of the tube and this nozzle having a maximum diameter which is greater than the diameter of the seal means when the seal means is in an unstressed condition. This obviously allows insertion of the nozzle and the seal means into a valve without the seal means engaging the valve which could possibly prevent full insertion of the connector.

Preferably, the nozzle will have a shoulder adjacent to the seal means and this shoulder will usually present a face perpendicular to the tube and which face abuts the

seal means.

In addition, the body will preferably have a circular cross section and be tapered so as to increase in diameter as it extends longitudinally away from the nozzle, the smallest diameter of the body being adjacent to the seal means and having a diameter which is again greater than the diameter of the seal means when the seal means is in an unstressed condition.

The connector may also comprise a spigot disposed at opposed ends of the tube, whereby the tube passes through two support bodies and two seal means so that each seal means is disposed between a nozzle and a body and the connector has two independent displacement means one each provided to displace each of the bodies longitudinally relative to the tube to cause the body and nozzle disposed either side of a seal means to engage and stress that seal means to deform each seal means radially outwardly relative to the tube for engagement with the sockets in which the spigots may be received. In this manner each spigot will have a seal means which may be deformed independently of the other seal means by independent displacement of each of the bodies towards the respective spigots. It will be appreciated that connectors having the spigots disposed at each end of the tube will provide a through connection. It is also envisaged that "T - junctions" or alternative spigot connectors incorporating deformable seal means and moveable bodies towards their free ends may be constructed according to the present invention.

As an alternative, the spigoted connector may simply have an attachment means disposed at the opposite end of the tube to the spigot, whereby this attachment means may be simply attached to a connector or a pipe. Such

attachment means may comprise simple screw connections or simple friction connectors. The present invention, in its preferred form, is applied to an adaptor for connecting an inflator device to a valve. Such an adaptor will usually have an attachment means for attachment to a pipe leading to the inflator device.

One embodiment of a Spigoted Connector, in the form of an adaptor for connecting an inflator device to a valve, in accordance with the present invention will now be described, by way example only, with reference to the accompanying illustrative drawings in which:-

Figure 7 is a perspective view of the adaptor in an unactuated state;

Figure 8 is a cross section of the adaptor taken along the line II - II of Figure 7;

Figure 9 is a side elevation of the adaptor of Figure 7 in an actuated state; and

Figure 10 shows a further embodiment of the adaptor of Figure 1.

As seen in Figure 7 an adaptor 50 comprises a longitudinally extending tube 52 (Figure 8) having a tapered nozzle 34 securely attached to one end 35. This nozzle 34 has a circular cross section and is axially mounted about the tube 52. The nozzle 34 increases in diameter from the end 35 longitudinally along the length of the tube 52 and ending in a shoulder which presents a flat face 36 extending perpendicular to the tube 52.

At the opposite end 18 of the tube 52 is fixedly

mounted a pipe connector 20 for conventional frictional connection with a pipe (not shown). Disposed inwardly of the end 18 of the pipe 52 is a flat handle 22 which is substantially "D" shaped in profile. This handle is fixed relative to the tube 52 and has, at a side 24 remote from the end 18 of the tube 52, a rope threaded portion 26 which is cylindrical in cross section and axially mounted about the axis 21 of the tube 52 and sealed to the tube 52. This rope threaded portion 26 has a cross section substantially greater than the tube 52. The handle 22, threaded portion 26, nozzle 34 and connector 20 are all fixed to the tube 52 so as to be rotational therewith as a uniform body.

A resiliently deformable spherical seal 80 is mounted circumferentially about the tube 52 adjacent to the shoulder 36 of the nozzle 34. This seal 80 is substantially spherical in shape and is made of silicone rubber. This seal 80, although mounted on the tube 52, is free to rotate about the tube and is not fixed to either the tube or the nozzle 34. The diameter of the seal 80 is less than the largest diameter of the nozzle 34.

A support body 70, having a substantially cylindrical cross-sectional area, is also axially mounted about the tube 52. The support body 70 has a complementary, cylindrical aperture 42 extending longitudinally along its central axis through which the tube 52 passes in a complementary fit. This body 70 is disposed between the spherical seal 80 and the handle 22 and is rotatable about the tube 52. This body 70 has an outer diameter adjacent to this spherical sphere 80 comparable with the greatest diameter of the nozzle 34 and the diameter of this body 70 increases non uniformly as it increases in longitudinal distance from the end of the tube 52 until a constant uniform diameter is achieved adjacent to the handle 22,

providing the body 70 with a substantially bottle neck shape.

The central passage 42 of the support body 70 increases substantially in diameter away from the end 35 of the tube 52 and is provided with a reciprocal screw thread for achieving a complimentary screw threaded engagement with the rope threaded portion 26 of the handle 22.

In use, the adaptor 50 will be connected to a conventional inflator device, such as hand pump (not shown), with the aid of a flexible pipe (not shown) which is frictionally attached to the connector 20 in a conventional manner. Although the pipe connector 20 is shown here as a simple friction engaging device, and it will be appreciated that a more stable connector may be employed such as a clip-on connector or a screw threaded connector. The nozzle 34 of the adaptor 50 is then inserted into a valve socket (not shown). A typical valve for which this adaptor is to be used will consist of a simple inflation canal of a resilient material (such as silicone rubber) whereby the inflation canal will have on its inner surface two side welds to form a venturi and the adaptor 50 is inserted so that the spherical seal 80 is disposed between the two welds within the canal. It will also be appreciated that should a rigid valve be used it will still be possible to have such welds to form a venturi therein. However, this present adaptor does not necessarily need a venturi formed within the valve.

In use the nozzle 34 is fully inserted into the valve, and the handle 22 is rotated anti clockwise (as shown in Figure 7) relative to the support body 70 through substantially 90° to reach the position shown in Figure 9. This rotation causes co-operation between the screw

threaded portion 26 and the screw threaded portion of the body 70 so as to displace the body 70 longitudinally along the length of the tube 52, causing part 44 of the threaded portion 26 to be withdrawn longitudinally out of the central passage 42 of the body 70 (Figure 9). This displacement of the body 70 relative to the tube 52 also serves to draw the shoulder face 36 of the nozzle 34 towards a shoulder 46 of the body portion 70 which serves to compress the deformable seal 80 therebetween, causing the diameter of this seal to increase significantly 80' (as shown in Figure 9). This increase in the diameter 80' of the seal 80 will either expand the resilient material of the valve causing the seal to press firmly against the surrounding parts of the valve to create a hermetic union, or, where there is a rigid valve, to form a compressed seal between the seal 80' and the valve. By expanding the seal 80 in the valve in this manner a much firmer engagement is obtained between the adaptor 50 and the valve, greatly increasing the frictional retaining forces between the adaptor and the valve and the engagement of the seal means 80' with the venturi further increasing the retaining forces between the valve and the adaptor 50. This increases in retaining force over conventional frictional engagement between a valve and adaptor allows an object to be safely inflated to higher internal pressures than normally achievable.

This valve is intended to be used with a speculum which may be inflated using a conventional hand pump, whereby the pump is fitted with a one way release valve so that air pumped into the adaptor 50 passes through its hollow tube 52 and pressurises the speculum, the pressurised gas within the speculum being unable to escape back past the seal 80, with the release valve in the pump serving to prevent pressure escaping back through the tube

52.

It will be appreciated that there are numerous further embodiments of the present invention, which should not be restricted to the preferred embodiment herein described. Although we have directed the preferred embodiment to an adaptor for an inflator device it will be appreciated that the concept of increasing the diameter of the seal by relative displacement between the body and a tube to compress the seal can be used in a conventional spigot connector for connecting pipes together, both rigid and flexible pipes. In addition, although we have described the means of displacing the body 70 relative to the tube 52 as employing a conventional screw threaded mechanism it will be clear to those skilled in the art that other types of displacement means may be employed, such as reciprocal cam surface mechanism (such as conventional bayonet fittings) or, especially in the case of larger spigoted connectors, a conventional ratchet mechanism may be used to displace a body 70 relative to the tube 52. Such a ratchet mechanism could incorporate an array of notches on the tube itself and the body 70 having a lever operated engagement means whereby operation of the lever could bring the engagement means in to engagement with the notches to effect longitudinal displacement of the body relative to the tube in the required direction.

Although in the present embodiment a spherical seal 80 is employed together with a spherical nozzle it will be appreciated that the cross sectional shape of the components of the spigoted connector maybe varied for differing requirements and valve/socket shapes.

Furthermore, the present adaptor only relates to a single deformable seal 80. However, it is envisaged that a connector 50' (Figure 10) may comprise two nozzles 121, 122, one fixed to oppose ends of a tube 52'. Such a connector incorporates a central portion 142 fixed to the tube 52' with two seal means 130, 140, one each disposed adjacent to each nozzle 121, 122 respectively and two bodies 147, 149 axially mounted about the tube 52', one each disposed either side of the central portion 142. It will be clearly understood from Figure 10 that the adaptor 50' comprises two nozzle and seal deformation devices as shown in Figure 7 which have been connected back to back and both seals 130, 140 at opposite ends of the adaptor 50' can be deformed independently using the procedure described with reference to the adaptor 50 of Figure 7.

This concept can be taken further whereby "T-junction" spigot connectors (or multiple spigot connectors) can have this deformable seal mechanism associated with each spigot.

It will be appreciated by persons skilled in the art that numerous variations and/or modifications may be made to the invention as shown in the specific embodiments without departing from the spirit or scope of the invention as broadly described. The present embodiments are, therefore, to be considered in all respects as illustrative and not restrictive.

CLAIMS

1. An inflatable vaginal speculum (10) comprising an inflatable elongate member (12), the elongate member (12) being adapted for insertion into the vagina when uninflated, the inflation of the elongate member creating a passage (18) through the member (12) which resists occlusion due to the force applied to the member by the vaginal walls.

2. An inflatable speculum as claimed in Claim 1 comprising an elongate member (12), an array of the inflatable chambers (16) extending along the inner surface of the elongate member (12), and an air inlet means (14) to enable inflation of the chambers (16) characterized in that the inflatable chambers (16) are arranged such that, upon inflation, they bear against each other so as to hold the elongate member open and provide a clear passage (18) through the member (12).

3. An inflatable speculum as claimed in Claim 2, wherein the inflatable chambers extend diagonally along the length of the elongate member.

4. An inflatable speculum as claimed in any preceding Claim, wherein the uninflated speculum (10) is wrapped by an extended piece of material (61) contiguous with the elongate member (12).

5. An inflatable speculum as claimed in Claim 4, wherein the uninflated speculum is provided with a cap (62).

6. A connector for inflation of a device and adapted to be placed between the source of inflating fluid and the inlet of the device to be inflated comprising a longitudinally extending tube (52) having a spigot (34) at one end thereof, said tube extending through a support body (70) and a resiliently deformable seal means (80) whereby said seal means (80) is disposed between said body (70) and said spigot (34), and displacement means (26) being provided to displace said body (70) longitudinally relative to said tube (52) towards the spigot (34) causing said body (70) and spigot (34) to engage and stress the seal means (80) to deform it radially outwardly relative to the tube for engagement with a socket in the device to be inflated in which the spigot (34) may be received.

7. An apparatus as claimed in Claim 6, comprising a first cam or threaded surface on the tube (52) and a second can or threaded surface on an inner surface of the body (70) so that relative rotation between the body (70) and the tube (52) will cause the first and second cam or screw surfaces to come into engagement with one another and effecting relative longitudinal displacement between the tube (52) and the body (70), forcing the body (70) towards the spigot (34).

8. An apparatus as claimed in Claim 6 or Claim 7, wherein the spigot comprises a nozzle which will have a circular cross section which increases in diameter as it extends longitudinally inwardly from the end of the tube (52) and this nozzle having a maximum diameter which is greater than the diameter of the seal means when the seal means (80 is in an unstressed condition.

9. An apparatus as claimed in Claim 6 which comprises a spigot (34) disposed at opposed ends of the tube (52), whereby the tube (52) passes through two support bodies (70) and two seal means (80) so that each seal means (80) is disposed between a nozzle (34) and a body (70) and the connector has two independent displacement means (26) one each provided to displace each of the bodies longitudinally relative to the tube to cause the body (70) and nozzle (34) disposed either side of a seal means (80) to engage and stress that seal means (80) to deform each seal means radially outwardly relative to the tube for engagement with the sockets in which the spigots may be received.

10. An apparatus as claimed in any one of Claims 6 to 9 for use in the inflation of a speculum as defined in Claim 1.

11. A kit of parts comprising an inflatable vaginal speculum as claimed in any one of Claims 1 to 5, an air pressure insurflater bulb and a connector as claimed in any one of Claims 6 to 9.

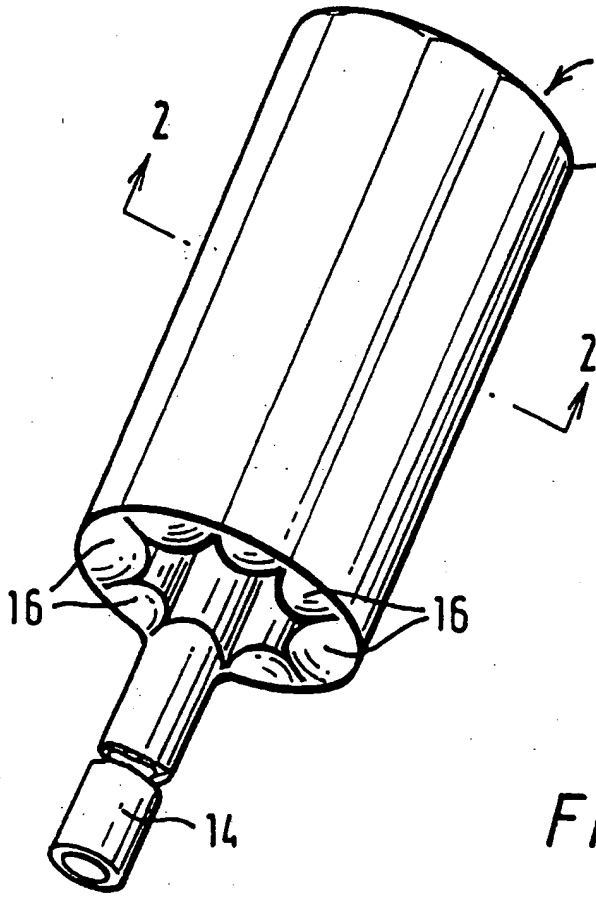


FIG. 1

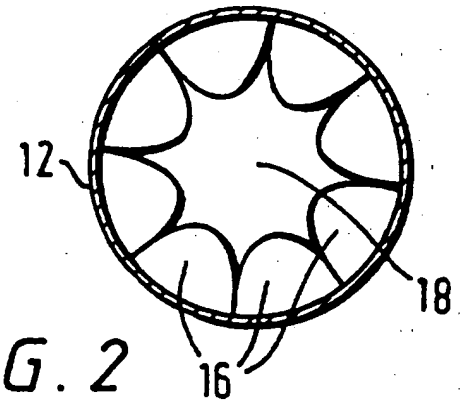
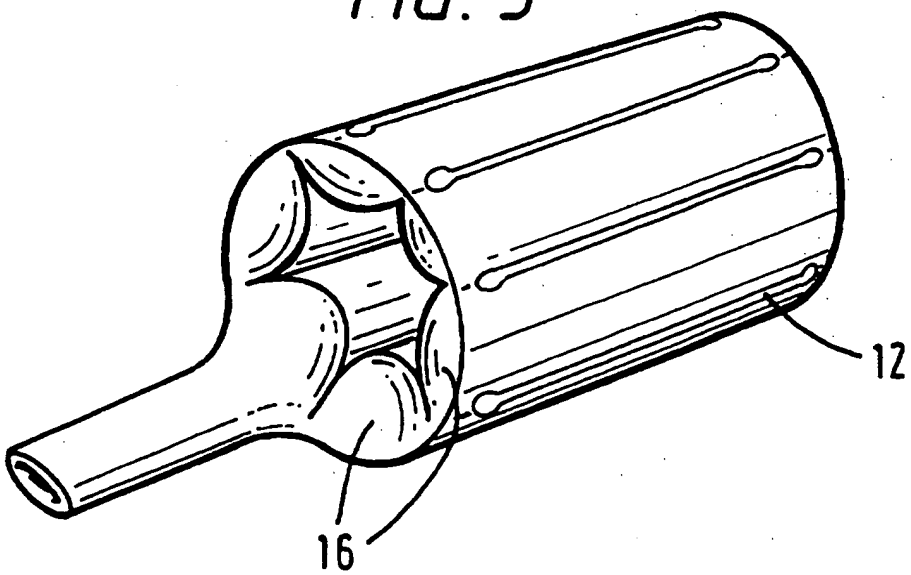


FIG. 2

FIG. 3



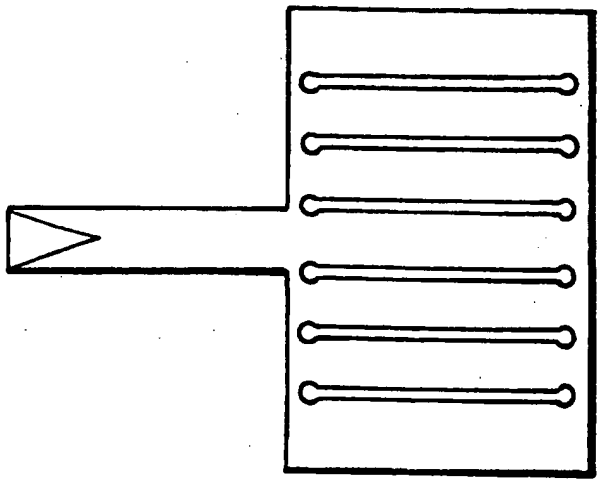


FIG. 4

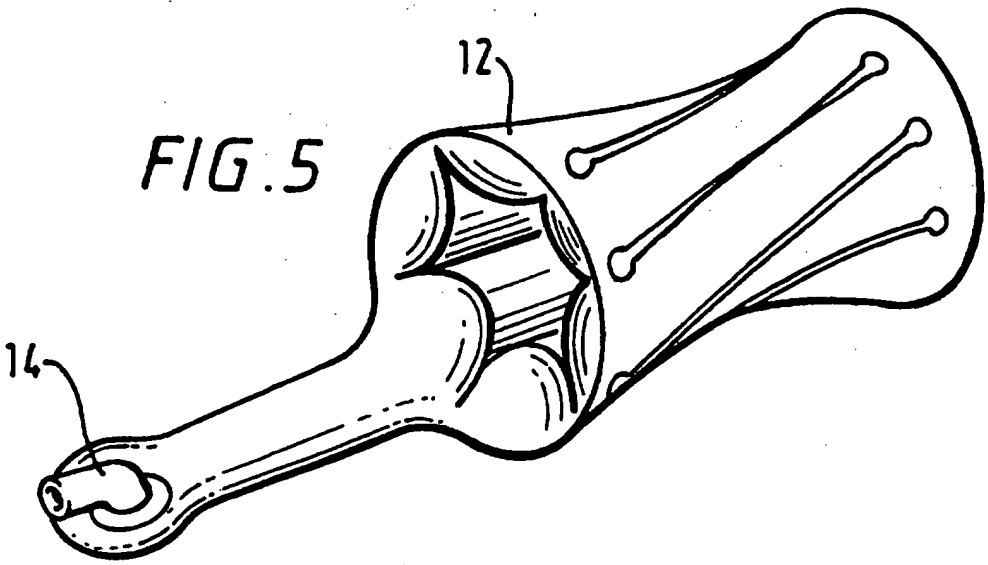
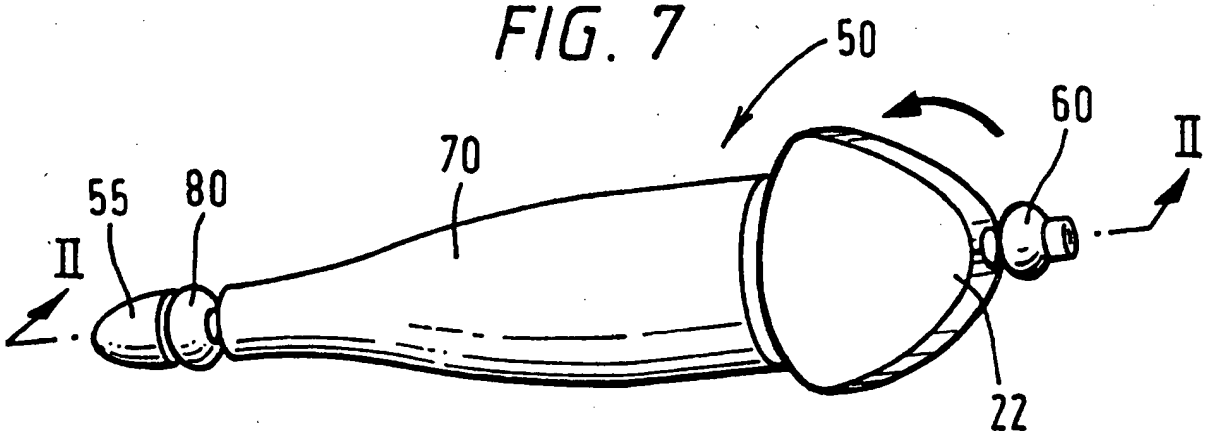


FIG. 5

FIG. 7



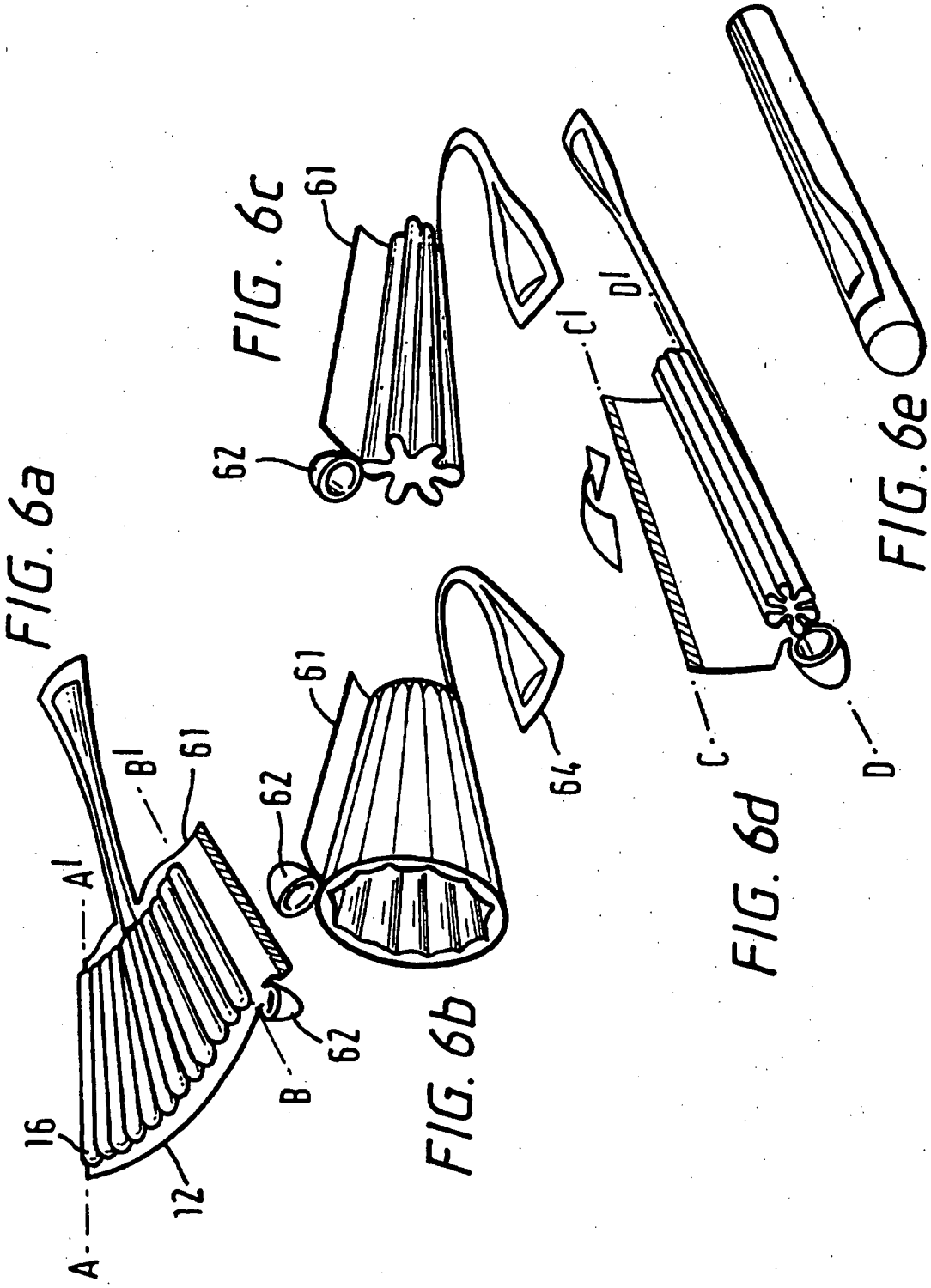


FIG. 6a
A
A'
B'
B
16
12
61
62
FIG. 6b
61
62
64
FIG. 6c
61
62
FIG. 6d
C'
D'
C
D
FIG. 6e

FIG. 8

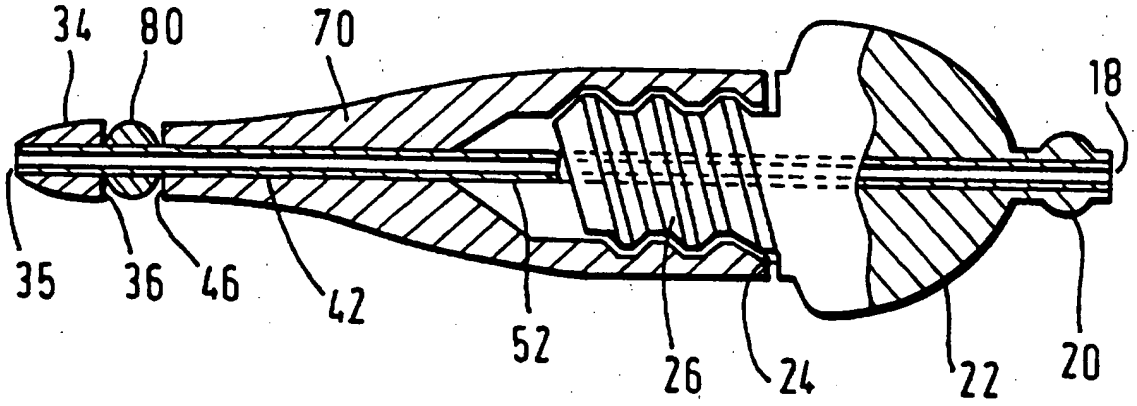


FIG. 9

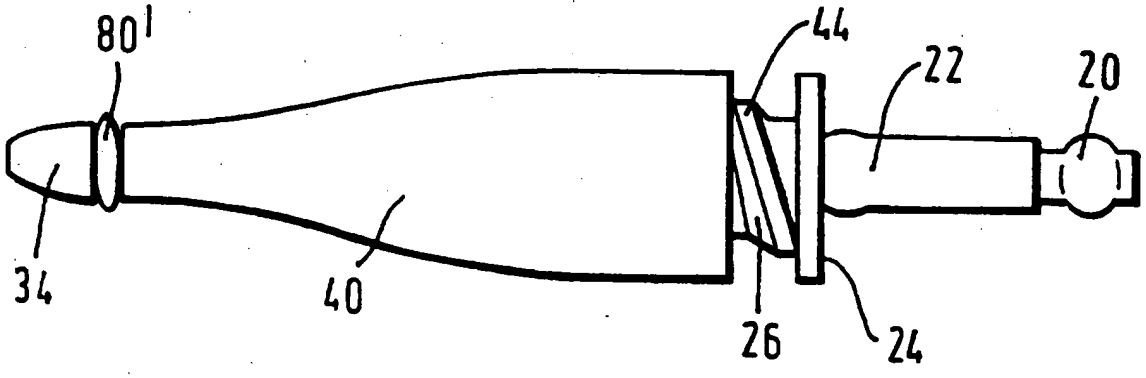


FIG. 10